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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,943	02/21/2002	Carlos R. Plata-Salaman	ORT-1578	4471

27777 7590 04/10/2003

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EXAMINER	
JARVIS, WILLIAM R A	

ART UNIT	PAPER NUMBER
1614	6

DATE MAILED: 04/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/081,943	Applicant(s) PLATA-SALAMAN ET AL.	
	Examiner William R. Jarvis	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-27 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-27 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-27 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-26 of copending Application No. 10/192,973, claims 1-26 of copending Application No. 09/906,251, and claims 1-40 of copending Application No. 10/193,600. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present invention and the copending applications all claim methods of treatment of pain with the same compounds. Although the present application claims pain broadly, while the copending applications claim treatment of neuropathic pain and cluster and migraine headache-associated pain, the claims of the present invention are clearly made obvious by the claims of the copending applications since treatment of neuropathic pain and cluster and migraine headache-associated pain is clearly encompassed by treatment of pain broadly. Furthermore, dependent claims of the present invention include specific types of pain that are also claimed in the copending applications. See, for example, claim 26 of the present invention and claim 20 of each of the first two copending applications and claim 30 of the third copending application, which all claim treatment of pain caused by headache, migraine, trigeminal neuralgia, spinal cord injury, etc.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over applicant's submitted references Hansen, Swerdlow, Beghi, or Magnus, each in view of U.S. Patent 6,103,759 (Choi et al). Hansen states, "Antiepileptic drugs (AEDs) as a class have been widely studied and prescribed for the relief of acute and chronic pain. In general, there is the greatest support for the efficacy of AEDs in the treatment of trigeminal neuralgia and diabetic neuropathy and for migraine prophylaxis."; see page 646, column 2. Similarly, Swerdlow teaches that the use of anticonvulsant drugs such as phenytoin and carbamazepine has been successful in the treatment of various types of pain including the claimed trigeminal neuralgia; see pages 51-56 in particular. Beghi teaches the use of anticonvulsant drugs such as carbamazepine and valproic acid for the treatment of trigeminal neuralgia and other neuropathic pain, migraine, and chronic pain; see pages 64-70 in particular. Magnus teaches the use of the antiepileptic drug gabapentin for the treatment of neuropathic pain, postherpetic neuralgia, diabetic neuropathy, trigeminal neuralgia, and in migraine prophylaxis; see pages S66-S68 in particular.

Applicant's claimed invention differs from the primary references in that it requires certain carbamate compounds for treatment of pain. However, the patent to Choi teaches that the claimed compounds, either in the form of the racemic mixture or as individual enantiomers, are

effective anticonvulsive/antiepileptic agents; see columns 3 and 4 in particular. One skilled in the pharmaceutical arts would have been motivated to treat pain with the claimed carbamate compounds, since at the time of applicant's invention, antiepileptic drugs, the class of compounds to which the claimed compounds were known to belong, had been used to treat various types of pain. Some claims additionally differ in that they require a particular enantiomer of the compound. However, since the patent to Choi includes the use of enantiomers in high purity, these claims are clearly made obvious thereby. Although some dependent claims also differ in that they require treatment of types of pain not taught by the prior art, these claims are nevertheless obvious since it is within the skill of the pharmaceutical artisan to treat various types of pain similarly. The claimed amounts or dosages are obvious since it is within the skill of the pharmaceutical artisan to determine the amount or dosage of a drug that provides the therapeutic effect most effective for treating the patient's condition while minimizing adverse side effects.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William R. Jarvis whose telephone number is 703-308-4613. The examiner can normally be reached on Monday, Tuesday, Thursday & Friday 7:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne C. Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

William R. Jarvis
Primary Examiner
Art Unit 1614

wrj
April 9, 2003